

## **REMARKS**

### **Introduction**

Claims 5-7, 12-14, and 17-18 are pending. Claims 5, 7, 12, and 14 have been amended and new claims 17 and 18 have been added. Support for these amendments and new claims can be found throughout the specification, for example, in the claims as filed; in the specification at page 6, line 17 and line 26; and in Examples 5 and 6. These changes are not believed to introduce new matter.

Claims 1-4, 8-11, and 15-16 have been cancelled without prejudice to the subject matter therein. Applicant expressly reserves the right to pursue the subject matter of these claims later in this application or in another application.

### **Rejection under 35 U.S.C. §101**

The Examiner has rejected claims 1-4, 8-11, 15 and 16 under 35 U.S.C. §101 as allegedly being improper process claims. Applicant respectfully traverses.

To expedite prosecution, these claims have been cancelled herein. This rejection is moot. Withdrawal of the rejection under 35 U.S.C. §101 is respectfully requested.

### **Rejections under 35 U.S.C. §112**

#### **A. Indefiniteness**

The Examiner has rejected claims 1-4, 8-11, 15 and 16 under 35 U.S.C. §112 second paragraph as allegedly being indefinite. Applicant respectfully traverses.

To expedite prosecution, these claims have been cancelled herein. This rejection is moot. Withdrawal of this rejection under 35 U.S.C. §112 is respectfully requested.

B. Enablement - Derivatives

The Examiner has also rejected claims 1-16 under 35 U.S.C. §112 first paragraph as allegedly lacking enablement for pharmacologically acceptable derivatives of aivlosin. Applicant respectfully traverses.

To expedite prosecution, the claims have been amended to remove the language pertaining to derivatives of aivlosin and replace it with salts of aivlosin. Such salts of aivlosin are enabled by the specification, for example, the use of an example of a salt, aivlosin tartrate, is discussed on page 6, line 17 and line 26. This rejection is moot. Withdrawal of this rejection under 35 U.S.C. §112 is respectfully requested.

C. Enablement – Infections

The Examiner has rejected claims 1-16 under 35 U.S.C. §112 first paragraph because the specification allegedly lacks enablement for the prevention of infections due to *Brachyspira pilosicoli* or *Ornithobacterium rhinotracheale*. Applicant respectfully traverses.

To expedite prosecution, the claims have been amended to recite "method[s] of treating or controlling a disease" due to either *Brachyspira pilosicoli* (claim 5 and its dependent claims) or *Ornithobacterium rhinotracheale* (claim 12 and its dependent claims). The specification, for example in Examples 7 and 8, discloses that aivlosin can prevent *Brachyspira pilosicoli* and *Ornithobacterium rhinotracheale* from establishing a colony. If the bacteria cannot establish a colony in the presence of aivlosin, one of skill in the art will appreciate that the bacteria will not be able to cause disease permitting the treatment and/or control of that disease. The specification further provides example dosages and durations of administration for using aivlosin to treat or control the claimed diseases on page 7, lines 1-11. Therefore, Applicant respectfully submits that the amended method claims are fully enabled. This rejection is moot.

For at least the above reasons, all of the rejections under 35 U.S.C. §112 have been overcome or rendered moot. Withdrawal of these rejections is requested.

**Rejection under 35 U.S.C. §102**

The Examiner has rejected claims 1-16 under 35 U.S.C. §102(b) as allegedly being anticipated by WO 02/32233 (the '233 publication). Applicants respectfully traverse.

The pending claims are directed to methods of treating or controlling diseases due to either *Brachyspira pilosicoli* or *Ornithobacterium rhinotracheale*. As stated in MPEP § 2112, "[i]n relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990).

The Examiner has not provided evidence from the '233 publication or other document that demonstrates that aivlosin should be administered to treat or control the claimed diseases in animals in need of such treatment. In fact, as the Examiner notes on page 6 of the Office Action, the treatment or control of disease due to *Brachyspira pilosicoli* or *Ornithobacterium rhinotracheale* is not disclosed in WO02/32233. The Examiner has simply not provided enough evidence to establish a prima facie case that administration of aivlosin as disclosed in the '233 publication would necessarily treat the claimed diseases due to *Brachyspira pilosicoli* or *Ornithobacterium rhinotracheale*.

Therefore, the rejection under 35 U.S.C. §102(b) is improper. Withdrawal of this rejection is requested.

**Rejection under 35 U.S.C. §103**

The Examiner has rejected claims 1-16 under 35 U.S.C. §103(a) as allegedly being unpatentable over the '233 publication. Applicant respectfully traverses.

As the Examiner notes on page 6 of the Office Action, the treatment of disease due to *Brachyspira pilosicoli* or *Ornithobacterium rhinotracheale* is not disclosed in WO02/32233. There

is no express teaching in the '223 publication to indicate that aivlosin would be effective in treating or controlling diseases due to *Brachyspira pilosicoli* or *Ornithobacterium rhinotracheale*. Without such an express teaching, one of skill in the art would not be motivated to administer aivlosin to animals having a disease due to *Brachyspira pilosicoli* or *Ornithobacterium rhinotracheale* to control or treat the disease as the claims require. Therefore, a prima facie case of obviousness has not been made.

Yet, the Examiner alleges that aivlosin is known for the treatment of microbial infections in pigs and poultry and therefore it would be obvious to use aivlosin to treat *Brachyspira pilosicoli* and *Ornithobacterium rhinotracheale*. Applicant disagrees because the ability of an antibiotic known to treat or control a first microorganism does not predictably indicate efficacy against a second distinct microorganism. For example, Pulmotil is an antibiotic administered to animals like aivlosin, but is described in the present application as being significantly less effective than aivlosin against *Ornithobacterium rhinotracheale*. See Example 8. This demonstrates the unpredictability of the efficacy of antibiotic agents. Therefore, it cannot reasonably be expected that aivlosin would be successful in treating or controlling disease due to *Brachyspira pilosicoli* and *Ornithobacterium rhinotracheale* based on the disclosure of the '233 publication alone.

For at least these reasons, the pending claims are not obvious in view of the '233 publication. Withdrawal of the rejection under 35 U.S.C. §103(a) is respectfully requested.

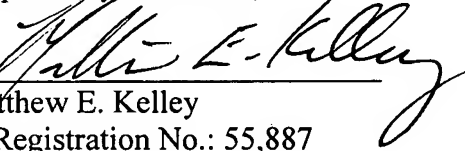
### CONCLUSION

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. Accordingly, Applicants request that the Examiner issue a Notice of Allowance indicating the allowability of claims 5-7, 12-14, and 17-18 and that the application be passed to issue. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is hereby invited to telephone the undersigned at the number provided.

The Commissioner is authorized to charge any deficiency in any patent application processing fees pursuant to 37 CFR §1.17, including extension of time fees pursuant to 37 CFR §1.17(a)-(d), associated with this communication and to credit any excess payment to Deposit Account No. 22-0261.

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Respectfully submitted,

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